REMARKS

The claims previously in the case have been replaced by new claims that are believed to be proper as to form and clearly patentable over the cited references.

In drafting the new claims, careful attention was paid to the Examiner's criticisms of the form of the previous claims, all of which criticisms are believed to be met by the new claims.

The new claims also are drawn with greater precision to the unobvious subject matter of the present application.

Reconsideration is accordingly respectfully requested, for the rejection of the claims as anticipated by or unpatentable over NEBOLON, alone or in view of GERIG.

Although NEBOLON's invention and the present invention both use hinge joints and connecting straps, in both inventions the purpose and the mechanism by which each invention functions is entirely different.

The function of the NEBOLON invention is to resist valgus or varus rotation of a knee joint or twisting of the knee axially about the limb (NEBOLON column 7, lines 43–49). It cannot resist nor does it describe a mechanism capable of resisting extension or fiexion of the same joint, which is the function of the present invention. According to NEBOLON, in the case of the human knee joint, the effect is to support the Medial Collateral Ligament (MCL) and the Lateral Collateral Ligaments (LCL) (NEBOLON column 7, lines 3-29). The function of these

ligaments in a healthy knee joint is to keep the joint action straight and prevent lateral deviation by an abnormal, crooked, non-linear valgus or varus joint movement. However, if these ligaments are injured or weakened there is an abnormal, non-linear valgus or varus rotation of the knee and the MCL and LCL become excessively loaded. NEBOLON's invention specifically resists lateral deviation of the joint (NEBOLON column 7, lines 43–49). NEBOLON's invention does not provide resistance to linear extension or flexion of the joint, which is the function of the present invention (DALY page 6, lines 5–6). The two inventions are also very distinct in terms of the mechanisms they use.

NEBOLON achieves a resistance to abnormal lateral deviation of the joint by using the two substantially unstretchable straps 14 and 16, which pass diagonally above and below the apex of the joint (kneecap), to either side of the joint (NEBOLON column 6, lines 51-54, column 8, lines 35-45). If the joint twists axially about the limb or deviates non-linearly in valgus or varus rotation from normal joint rotation, these diagonal straps become loaded and thereby resist vaigus or varus rotation and twisting of the joint (NEBOLON column 7, lines 43–49). The inventor has found from experimentation that this strap arrangement described by NEBOLON cannot resist, nor does NEBOLON claim it resists, normal linear flexion or extension and therefore cannot support the muscles and tendons involved in

linear flexion or extension of the joint, which is the function of the present invention.

The function of the present invention is specifically to resist extension of a joint. In order to resist flexion or extension of the joint it is absolutely essential that the recited "essentially inelastic means" or "tensile artificial tendon" be arranged to the posterior side of the joint, i.e. in practice to pass directly over the apex (along the palmar aspect of the metacarpus and digit (DALY page 12, lines 30– 34) of the joint. If the straps are located laterally at the side of the joint, as NEBOLON's are, they allow the apex (palmar aspect) of the joint, or "skeletal protrusion" as he describes it, to pass through the opening between straps (NEBOLON column 6, lines 60–64). The effect of this geometric arrangement of straps is that, while it would limit abnormal lateral valgus or varus deviation of a joint, there is no means of limiting extension of the joint. Indeed, the use of NEBOLON's device would have no ability whatsoever to reduce tendon strain in exercising horses. This is not only due to the differences of geometric construction described here, but also because of the enormous load that is exerted on equine flexor tendons during exercise –tensile loads of 1.5 to 2 tons are typically experienced during high-speed equine locomotion, far above loads experienced by any tendon in a human athlete. The NEBOLON construction cannot resist, and indeed is not designed to resist, this extremely high level of

tensile load experienced during high-speed equine locomotion. In fact, senior scientists at the Royal Veterinary College in England (Prof. Roger Smith, A. M. Wilson et al.) carried out a comparison study of the effectiveness of all methods currently in existence to resist fetlock joint extension for the purpose of supporting equine flexor tendons. The results of these tests, which were published in the Equine Veterinary Journal in November 2002, concluded that the present invention is the first tendon support method available capable of significant reduction of flexor tendon strain in exercising horses (Equine Vet. J. 2002 34(7) 726-731).

As the function of the present invention is specifically to resist linear extension of a joint, in so doing it prevents excessive tensile load being applied to the flexor tendons, and as in the case of a horse's fetlock joint the suspensory ligament also (DALY page 6, lines 5–6). It specifically does not resist an abnornmal and crooked valgus or varus rotation of the same joint (DALY page 7, lines 26–29), which by contrast is specifically the function of NEBOLON's invention.

The mechanism and construction of GERIG is entirely different from the present invention. The unitary construction of the brace totally immobilizes the joint so that it does not allow free flexion of the joint while resisting extension of the joint. This is in contrast to the mechanism of the present invention

which while resisting and limiting extension of the joint does allow the same joint to flex in an unrestricted manner (DALY page 6, lines 4–6).

The references cited but not applied are in more remote from the present invention than are those discussed above.

Thus, the function of PETERS, as with NEBOLON, is specifically to resist an abnormal lateral deviation of a joint (inversion or eversion of a human ankle) while not resisting flexion or extension of the joint (PETERS column 1, lines 6-12, lines 51–54). This is in total contrast to the function of the present invention. Not only is the purpose different but also the mechanisms by which it is achieved. The geometry of hinge and strap is entirely different in the two inventions and neither is capable of doing the same job as the other. The purpose of the strap in PETERS' invention is merely to hold the device in place and to help prevent lateral deviation or "inversion" of the joint (PETERS column 2, lines 20–26). Due to the reasons explained for NEBOLON, PETERS' arrangement of hinge and non-linear diagonal strap cannot resist the linear forces involved with extension or flexion of an equine fetlock joint during locomotion. In fact, PETERS specifically claims that his invention does not resist flexion or extension of the joint. (PETERS column 1, lines 51-52).

The device of CENTERS is not a means to resist flexion or extension of horse's joint during exercise. It is merely a

protective covering shield on the horse's leg to prevent damage that could be caused by self inflicted external impacts, from another of its own legs, while regaining consciousness after surgery or while standing in a horsebox in transit (column 1, lines 11–26). In fact, due to the manner in which it immobilizes the entire leg, the horse cannot exercise while wearing it and it is not intended for use during exercise. The "hinge" described in CENTERS' invention does not function as "a resistance-exerting pivot" in the same manner as in the present invention because of the extremely high loads involved during equine locomotion. CENTERS' invention does not describe a connecting means comprising the recited "essentially inelastic means" or "tensile artificial tendon" of the present invention to limit extension of a joint.

FARLEY does not, and does not claim to provide a mechanism to resist extension or flexion of a joint. Its specific function is to provide a veterinary treatment which corrects lateral valgus or varus deviation in a horse knee joint, and more specifically a foal, with abnormal and crooked joints. It achieves this by means of a hinged brace, which resists valgus or varus deviation by casting the joint in a correct position. FARLEY does not describe a connecting means comprising recited "essentially inelastic means" or "tensile artificial tendon" of the present invention to limit extension of a joint against the resistance of a resistance-exerting pivot.

RAINEY does not, and does not claim to provide a mechanism to resist extension or flexion of a joint. Its specific function is to support human knee joints which have been weakened as a result of paralysis, disease or other injury. It does this by means of a hinged brace which mimics the movement of the natural knee joint and which carries the weight of the person thereby removing weight from the weakened knee (column 1, lines 35–40). Although it comprises hinges, RAINEY's invention does not describe the recited "essentially inelastic means" or "tensile artificial tendon" of the present invention to limit extension of a joint against the resistance of a resistance-exerting hinge arrangement. There is a cable 76 connecting the two brace sections but this, because of its construction, cannot and is not intended for the purpose of resisting joint extension or flexion.

CLEGG does not, and does not claim to provide a mechanism to resist extension or flexion of a joint. The pivot in CLEGG is provided with ball bearings to allow it to rotate without resistance, rather than to exert resistance as in the present invention. Its specific function is to prevent the horse's legs coming in contact with one another during exercise and the possibility of causing injury. Neither does CLEGG describe a connecting means forming a tensile "artificial tendon" to limit extension of a joint.

The device of SCOTT is a single piece bandage made from

soft fabric, neoprene and Velcro. In scientific experimentation this device proved to be entirely ineffective at reducing tendon or ligament strain in exercising horses. This is because the soft materials from which it is constructed cannot resist the enormous tensile loads (1.5 to 2 tons) exerted on the tendons and ligaments during exercise.

As the new claims bring out these distinctions with ample particularity, it is believed that they are all patentable, and reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following items:

- new Abstract of the Disclosure
- copy of article by R. Smith, A.M. Wilson et al., "*In vitro* evaluation of nonrigid support systems for the equine metacarpophalangeal joint", Equine Veterinary Journal, 2002, 34(7), pp. 726-731.